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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,123	12/22/2000	Shigeaki Harayama	766.45	7919

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1655	6

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/742,123	Harayama et al.
Examiner	**Art Unit**
Arun Chakrabarti	1655

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jun 6, 2001 .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-5 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-5 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the exact starting material, the intermediate step(s) and the final step.

Claims 1- 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as indefinite because the instantly claimed method lacks a final process step that clearly relates back to the preamble. For the method of claim 1, the preamble of the instantly claimed method is drawn to a method for making libraries of hybrid polynucleotides while the final process step is that of double-stranded polynucleotide molecules are not used as starting materials and it is thus unclear as to whether the instantly claimed method is drawn to a method for making libraries of hybrid polynucleotides or rather double-stranded polynucleotide molecules are not used as starting materials. Method claim requires a last step or phrase in the

last step that states the accomplishments of the goals for the method which were stated in the method's preamble. Claim 5 lacks such a last step and is confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashions. See Ex parte Erlich, 3 USPQ2d1011, p.1011 (Bd. Pat. Applicant. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

Claim 1 is also rejected under 35 U.S.C. 112, second paragraph, over the recitation of the phrase, "double-stranded polynucleotide molecules are not used as starting material". It is not clear if a single-stranded molecule is used as starting material or a triple helix molecule is used as starting material or both the single-stranded molecule and the triple helix molecules are claimed. The metes and bounds of the claims are vague and indefinite.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim 1 is also rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

Claim 1 is narrative in form and replete with indefinite and functional or operational language. The step which goes to make up the method must be clearly and positively specified. The steps must be organized and correlated in such a manner as to present a complete operative method.

Claim 2 is confusing in the last two lines. It is not clear if the complementary is in the second type molecule or a separate molecule that is complementary to the second type molecule. The metes and bounds of the claim are vague and indefinite.

In claim 2, "The complementary sequence" lacks proper antecedent basis.

Claim is vague and indefinite over the recitation of the phrase, "prior" . It does not make sense because mutations cannot be introduced into a hybrid before it is formed.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Stemmer (U.S. Patent 6,180,406 B1) (January 30, 2001).

Stemmer teaches a method for making libraries of hybrid polynucleotide molecules in which double-stranded polynucleotide molecules are not used as starting materials (Column 55, lines 5-8 and Column 86, line 39 to column 88, line 3).

Stemmer teaches a method wherein two types of single-stranded polynucleotide molecules are used as starting materials and wherein the first-type molecule comprises stretches

of sequences containing one or more parts of homology and one or more parts of heterology to the complementary sequences of the second-type molecule (Column 86, lines 39-60).

Stemmer teaches a method wherein the single-stranded polynucleotide molecules are fragmented and used as templates for de novo polynucleotide synthesis to create hybrid polynucleotide molecules (Column 87, lines 8-12).

Stemmer teaches a method wherein mutations are introduced into hybrid polynucleotide molecules prior, during or after the production of the hybrid polynucleotide (Example 14, Cassette mutagenesis Section, Column 87, line 3 to column 88, line 3).

Stemmer teaches a method for making libraries of hybrid polynucleotide molecules, which comprises:

(I) preparing two single-stranded polynucleotide molecules comprising sequences which are complementary to each other (Example 14, Column 86, line 39 to Column 87, line 7 and Claim 1);

(ii) randomly or non-randomly fragmenting the two single-stranded polynucleotide molecules (Example 14, Column 87, lines 8-12). This step is inherently carried out by heating the reaction mixture to 70 degree centigrade and cooling,

(iii) incubating the fragmented molecules under conditions such that hybridization of fragmented polynucleotide molecules occurs and de novo polynucleotide synthesis on the hybridized molecules occurs (Example 14, Column 87, lines 13-17 and Claim 1),

(iv) denaturing the resultant elongated double-stranded polynucleotide molecules into single-stranded polynucleotide molecules (Claim 11a and b),

(V) incubating the resultant single-stranded polynucleotide molecules under conditions such that hybridization of fragmented polynucleotide molecules occurs and de novo polynucleotide synthesis on the hybridized molecules occurs (Claim 11c), and

(Vi) repeating at least two further cycles of steps (iv) and (v) (Claims 12 and 13).

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun kr. Chakrabarti

Arun Chakrabarti,

Patent Examiner,

November 20, 2001